

**DATE OUT:** 05/22/09

**SUBJECT: FEE      PRODUCT CHEMISTRY REVIEW OF MP [ ]   EP [X]**

**DP BARCODE No.:** D364738   **REG. No. /File Symbol No.** 56799-G

**PRODUCT NAME:** OSKU-HELLAS

**PCC:** 078201      **Decision No.** 219583

**FOOD USE [X]**

**COMPANY:** PRODUCTOS QUIMICOS Y ALIMENTICIOS OSKU S.A

**FROM:** Indira Gairola, Chemist  
Product Chemistry Team  
Technical Review Branch/RD (7505P)

**TO:** Bryant Crowe/ Tony Kish PM 22  
Fungicide Branch/RD (7505P)

#### **INTRODUCTION:**

PRODUCTOS QUIMICOS is seeking registration for the subject product OSKU-HELLAS.

Applicant has submitted a Basic CSF dated 03/05/09.

The submitted package was reviewed and details will be discussed below:

#### **SUMMARY OF FINDINGS:**

1. The subject product OSKU-HELLAS contains 73.5% of Anhydrous Sodium Bisulfite
2. PRODUCTOS QUIMICOS has submitted MRID #s 476996-01, -02 and -03 and 477145-01 for Product Chemistry data to support the registration of OSKU-HELLAS.
3. The source of active ingredient for the subject product is unregistered.
4. Basic CSF dated 03/05/09 for the subject product meet the label claim of 73.5% of Anhydrous Sodium Bisulfite.
5. Data corresponding Sub Group A do not satisfy the data requirements of 40CFR§158.320 to §158.355. Enforcement Analytical Method guideline series 830.1800 is not included with this submission.

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<u>PRODUCT CHEMISTRY DATA</u> <u>(SERIES 830 Subgroup A &amp; Subgroup B) Subgroup A</u>	<u>Data Required Fulfilled</u>	<u>MRID No.</u>
830.1550. Chemical Identity (Basic CSF)	A	Basic dated 03/05/09
830.1600. Beginning Materials	A	476996-02
30.1650. Formulation Process	A	476996-01
830.1670. Discussion of Impurities	A	476996-03
830.1700. Preliminary Analysis	NA	
830.1750. Certified Limits (Basic CSF)	A	Basic dated 03/05/09
830.1800. Enforcement Analytical Method	G	

6. Entire product chemistry data for Sub group A and Sub group B for the unregistered **Technical Sodium Bisulfite** must be submitted.
7. Product Chemistry Data for the Sub Group B for the proposed New Product have not been satisfied Data for guideline series 830.6314 to 830.6317, 830.6320, 830.7000 and 830.7300 have not been satisfied. It is stated that Storage stability / corrosion characteristics study data for 20 month period were observed. No results of actual % of recovery for Anhydrous Sodium Bisulfite are included. Data for 3, 6, 9 and 12 month intervals are a requirement.

### **CONCLUSIONS:**

TRB has reviewed the product chemistry data submitted for the above mentioned subject product and has concluded that:

1. The subject product OSKU-HELLAS contains 73.5% of Anhydrous Sodium Bisulfite.
2. The label claim is in compliance with PR Notice 91-2.
3. Basic CSF dated 03/05/09 for the subject product meets the label claim of 73.5% of Anhydrous Sodium Bisulfite is found to be acceptable.
4. The product chemistry data requirements for series 830 Sub Group A & B for the proposed new product are not satisfied and will be considered as data gaps. See findings # 5, 6 & 7.

<u>PRODUCT CHEMISTRY DATA</u> ( <u>SERIES 830</u> Subgroup B)	<u>Data Required Fulfilled</u>	<u>Value or Qualitat. Descrip.</u>	<u>MRID No.</u>
830.6302. Color	A	white	Unassigned
830.6303. Physical State	A	Solid crystals	Unassigned
830.6304. Odor	A	Pungent SO2 odor	Unassigned
830.6314. Oxidation/Reduction Action	G	Not stated	
830.6315. Flammability	G	Not stated	
830.6316. Explodability	G	Non stated	
830.6317. Storage stability	I	I	
830.6319. Miscibility	A	Water solubility 45% @ 20°C	Unassigned
830.6320. Corrosion Characteristics	I	I	
830.6321. Dialect. Bkd. Vltg.	NA		
830.7000. pH	UA	Acidic specify range.	Unassigned
830.7100. Viscosity	N/A		
830.7300. Density/Bulk Density	U	Specific gravity 1.5 specify units	Unassigned

Explanations: Y = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not applicable; G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.